K123366

JUL 1 2 2013

510(k) SUMMARY

Ellman International - Surgitron 4.0 Dual RF S5 - IEC

Submission Correspondent and Owner:

Name: Ellman International
Address: 3333 Royal Avenue
Oceanside NY 11572-3625

Phone: 513.658.8960
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Contact: Alison Sathe
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Date Prepared: October 25, 2012

Trade Name: Surgitron 4.0 Dual RF S5 - IEC

Common Name: Electrosurgical, cutting & coagulation & accessories

Classification: Class II, 21 CFR 878.4400, Product Code GEI

Predicate Devices: Ellman International – Surgitron 120 IEC (Surgitron 4.0 Dual RF) (K013255, K082834)

Device Description:
The Surgitron 4.0 Dual RF S5 – IEC is a radiofrequency energy generator employed for a variety of electrosurgical procedures. The action is achieved by selection of the desired waveform and power level on the front panel. Selections are activated by push buttons and indicated on the digital display giving the operator feedback on device setting status. Device output is controlled via foot and/or hand switch. Monopolar and bipolar electrodes may be used with the device. The generator includes the following accessories:

- IEC Power Cord
- Dual Footswitch & Cable
- IEC Foot controlled Handpiece
- Bipolar Cable
- Monopolar cables
- Disposable Neutral Plate
- Multi-Button Finger switch Handpiece

Indications for Use:
The Surgitron 4.0 Dual RF S5 - IEC is intended to deliver electrosurgical output to perform cutting, coagulation, and hemostasis of soft tissues and to heat tissue in the non-ablative treatment of mild to moderate facial wrinkles and rhytids. The device is used with compatible Ellman International electrodes and handpieces which are used for these various applications in physician offices and surgical centers.

The Surgitron 4.0 Dual RF S5 - IEC indications are the same as those cleared in K082835:

- Non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV
- Cutting: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags and blepharoplasty.
- Blended Cutting and Coagulation: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelidma, cosmetic repairs, cysts, abscesses, and development of skin flaps.
- Hemostasis: control of bleeding, epilation, telangiectasia.
- Fulguration: basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis.
- Bipolar: pinpoint precise coagulation, pinpoint hemostasis in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment and turbinate shrinkage.

Technological Characteristics:
The Surgitron 4.0 Dual RF S5 – IEC system consists of: RF generator, footswitch and cable, handpieces, neutral plate and cables (bipolar and power cord). The device operates at approximately 4 MHz and is used with various electrodes and handpieces to deliver RF energy to tissue. The Surgitron 4.0 Dual RF S5 – IEC has five modes of energy delivery which operate over a range of power outputs: cut, cut/coag (Blend), hemo (Coag), fulgurate, and bipolar.

Performance Data
The Surgitron 4.0 Dual RF S5 – IEC has been tested to IEC 60601-1 and 60601-2-2 standards. In all instances, the Surgitron 4.0 Dual RF S5 – IEC functioned as intended and in conformance with all applicable standards.

Substantial Equivalence
There are no unique applications, intended uses, materials or specifications presented herein. The Surgitron 4.0 Dual RF S5 – IEC is as safe and effective as the Surgitron 4.0 Dual RF – IEC

predicate device. The Surgitron 4.0 Dual RF S5 – IEC has the same intended uses, indications and principles of operation and similar technological characteristics as the predicate. The minor technological upgrades to the Surgitron 4.0 Dual RF S5 – IEC raise no new issues of safety or effectiveness. Thus, the Surgitron 4.0 Dual RF S5 – IEC is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 12, 2013

Ellman International, Inc.
% Ms. Alison Sathe
Director of Regulatory and Clinical Affairs
3333 Royal Avenue
Oceanside, New York 11572-3625

Re: K123366
Trade/Device Name: Surgitron 4.0 Dual RF S5 - IEC
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 12, 2013
Received: June 13, 2013

Dear Ms. Sathe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123366

Indications for Use: The Surgitron 4.0 Dual RF S5 – IEC is indicated for:

- Non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV
- Cutting: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags and blepharoplasty.
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Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF

Concurrence of CDRH, Office of Device Evaluation (ODE)

DSD—Division Sign-Off
Division of Surgical Devices
510(k) Number: K123366
Joshua C. Nipper -S